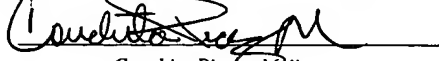


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Conchita Piccolo Mejia

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Leonard KATZ et al.

Serial No.: 10/690,949

Filing Date: October 21, 2003

For: RECOMBINANT *STREPTOMYCES*
HYGROSCOPICUS HOST CELLS THAT
PRODUCE 17-
DESMETHYLRAPAMYCIN

Examiner: Not Yet Assigned

Group Art Unit: 1652

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Pursuant to the USPTO notice dated July 11, 2003, waiving the requirement under 37 C.F.R. § 1.98 (a)(2)(i) to provide copies of U.S. Patents and U.S. Published Applications, a copy of reference number 7 is not submitted. A copy of reference number 15 is submitted herewith. However, copies of the remaining documents cited in the attached Form PTO-1449 were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial

Number 09/702,029, filed October 30, 2000 (now U.S. Patent No. 6,670,168,) and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. §1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make this document of record in the application.

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97(e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)


Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.300622005001. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 30, 2004

Respectfully submitted,

By: 
Randolph T. Apple
Registration No. 36,429

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5933
Facsimile: (650) 494-0792



PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

8+1
Reference

Application Number

10/690,949

Filing Date

October 21, 2003

First Named Inventor

Leonard KATZ

Art Unit

1652

Examiner Name

Not Yet Assigned

Attorney Docket Number

300622005001

ENCLOSURES (Check all that apply)☐ Fee Transmittal Form☐ Fee Attached☐ Amendment/Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement
(3 pages)☐ Certified Copy of Priority
Document(s)☐ Response to Missing Parts/
Incomplete Application☐ Response to Missing Parts
under 37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a
Provisional Application☐ Power of Attorney, Revocation
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) _____☐ After Allowance Communication
to Group☐ Appeal Communication to Board of
Appeals and Interferences☐ Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s) (please
identify below):

Form PTO-1449 + copy (4 pages)

One (1) reference

Return receipt postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENTFirm
or
Individual nameMORRISON & FOERSTER LLP (Customer No. 25226)
Randolph Ted Apple - 36,429

Signature

Date

March 30, 2004

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Signature

(Conchita Picazo-Mejia)

Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 300622005001

Application Number 10/690,949

Applicant

Leonard KATZ et al.

Filing Date October 21, 2003

Group Art Unit 1652

Mailing Date March 30, 2004



U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	09/30/1997	5,672,491	Khosla et al.			
	2.	10/20/1998	5,824,513	Katz et al.			
	3.	10/05/1999	5,962,290	Khosla et al.			
	4.	05/23/2000	6,066,721	Khosla et al.			
	5.	06/27/2000	6,080,555	Khosla et al.			
	6.	03/13/2001	6,200,813	Katz et al.			
	7.	12/30/2003	6,670,168	Katz et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	8.	10/28/1992	EP 0 510 904	Europe			
	9.	08/19/1993	WO 93/16189	WIPO			
	10.	08/31/1995	WO 95/22972	WIPO			
	11.	01/15/1998	WO 98/01546	WIPO			
	12.	11/05/1998	WO 98/49315	WIPO			
	13.	12/03/1998	WO 98/54308	WIPO			
	14.	04/13/2000	WO 00/20601	WIPO			
	15.	05/17/2001	WO 01/34816	WIPO			

OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	16.	Aparicio, J.T. et al. (1996). "Organization of the Biosynthetic Gene Cluster for Rapamycin in Streptomyces Hygroscopicus: Analysis of the Enzymatic Domains in the Modular Polyketide Synthase," <i>Gene</i> 169:9-16.

EXAMINER:

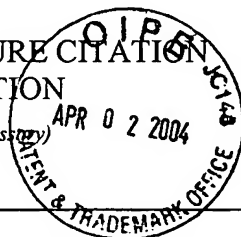
DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)



Docket Number 300622005001

Application Number 10/690,949

Applicant

Leonard KATZ et al.

Filing Date October 21, 2003

Group Art Unit 1652

Mailing Date March 30, 2004

- | | |
|-----|---|
| 17. | Lomovskaya et al. (1997). "Gene Disruption and Replacement in the Rapamycin-Producing Streptomyces Hygroscopicus Strain ATCC 29253," <i>Microbiology</i> 143:875-883 |
| 18. | Nelson, F.C. et al. (1999). "Manipulation of the C(922) - C(27) Region of Rapamycin: Stability Issues and Biological Implications," <i>Bioorganic & Medicinal Chemistry Letters</i> , 9(2):295-300. |
| 19. | Ruan, X. et al. (1997). "A Second Type-I PKS Cluster Isolated From Streptomyces Hygroscopicus ATCC 29253, a Rapamycin-Producing Strain," <i>Gene</i> 203:1-9. |
| 20. | Schwecke, T. et al. (1995). "The Biosynthetic Gene Cluster for the Polyketide Immunosuppressant Rapamycin," <i>Proc. Natl. Acad. Sci. USA</i> 92:7839-7843. |

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.